DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Nashville District Office
297 Plus Park Blvd.
Nashville, TN 37217

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4/20/99

April 20, 1999

CERTIFIED - RETURN RECEIPT REQUESTED

Alec Taylor, President
Chattem, Inc.
1715 West 38th Street
Chattanooga, TN 37409

WARNING LETTER - 99-NSV-10

Dear Mr. Taylor:

This letter is in reference to your firm's marketing and distributing of Echinex and Propalmex. Promotional material (labeling) makes therapeutic claims which cause the products to be drugs as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Examples of the claims include the following:

- **Echinex**...Support or boost "the body's natural resistance against infection" and..."viruses and bacteria won't even slow you down."

- **Propalmex**..."Most men over 45 experience a gradual increase in the prostate size at some time during or after middle age. Due to the fact that the prostate surrounds the urinary tract, an enlarged prostate can lead to an obstruction of urinary flow...can mean discomfort in urination or increased night-time urination" and "propalmex can help to support prostate health and promote free urinary flow."

The products are "new drugs" because there is no evidence that they are generally recognized as safe and effective for their intended uses [section 201(p) of the Act]. Therefore, they may not be legally marketed in this country without approved New Drug Applications [section 505(a) of the Act].

The drugs are also misbranded because their labeling fails to bear adequate directions for use for the conditions for which they are offered [section 502(f)(1) of the Act]. The labeling is false and misleading as it suggests that the products are safe and effective for their intended uses when, in fact, this has not been established [section 502(a) of the Act].

This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violation may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217

Sincerely,

Howard E. Lewis
Acting Director
Nashville District

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